



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

§ 1773d

**VIA FEDERAL EXPRESS**

Food and Drug Administration  
555 Winderley Pl., Ste. 200  
Maitland, FL 32751

Ref: Customs Entry No: J75-1032486-0 Line 001/001  
Product: Fresh Genips

**WARNING LETTER**

FLA-01-87

September 18, 2001

Mr. Wilfredo Sanchez, President  
Dade South Fruits and Vegetables, Inc.  
8700 NW 101<sup>st</sup> Street  
Medley, Florida 33178

Dear Mr. Sanchez:

The Food and Drug Administration (FDA), on August 20, 2001, attempted to examine a shipment of fresh genips in accordance with our Notice of FDA Action, dated August 19, 2001. The shipment was offered for import (imported) into the United States by your firm on August 18, 2001, under Customs' Entry Number J75-1032486-0. During our visual examination we noted that ninety cases (2,250 pounds) out of the original one hundred and fifteen cases were already distributed without a FDA release. Reportedly, these ninety cases of produce were brought back to your facility on, or about, August 27, 2001.

On August 28, 2001, we returned to your facility to verify the return of the ninety cases of genips previously distributed, and to verify that the entry was still held in tact. Our examination noted that not all the original product was available. There were still 1,000 pounds of product missing, and the Manager at your firm stated in an affidavit that some of the product had been sold to several customers in Maryland and New York. Not holding an entry in tact pending a FDA release is a violation of 21 CFR Section 1.90. This Section requires the importer to hold an imported article in tact, pending a release notice from FDA.

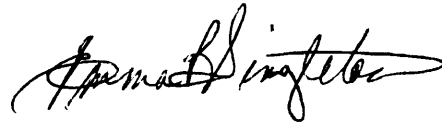
Failure to promptly correct this situation and prevent future premature distribution of imported product may result in requiring that future shipments be held in secured storage. Secured storage will be under the supervision and direction of U.S. Customs Service, such as in a bonded warehouse. You will be responsible for all costs incurred in secured storage.

We will be requesting that U.S. Customs Service order redelivery of the 1,000 pounds which were distributed without a FDA release. Failure to redeliver the missing portion to Customs custody may result in a penalty action at a later date.

We request a response in writing within fifteen (15) working days of receipt of this letter outlining the specific steps you have taken to correct the violation, including an explanation of each step being taken to prevent recurrence. In the event that the product is still available for examination, you should inform Customs and FDA if and when redelivery is accomplished.

Your written reply should be addressed to the Food and Drug Administration, Attention: Carlos W. Hernandez, Compliance Officer, P.O. Box 59-2256, Miami, Florida 33159-2256.

Sincerely,

A handwritten signature in black ink, appearing to read "Emma R. Singleton", with a stylized flourish at the end.

Emma R. Singleton  
Director, Florida District

cc: Thomas Winkowski  
Port Director  
U. S. Customs Service  
P. O. Box 02-580  
Miami, Florida 33102-5280